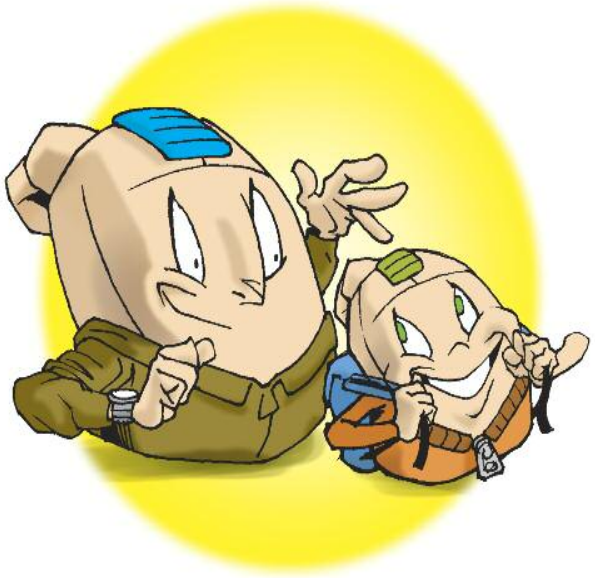

Tibco Unveils Solution for ACCELERATING DRUG DEVELOPMENT

Tibco Spotfire Clinical is an in-memory analytics platform that empowers clinical development teams to make fast, accurate decisions that enhance patient safety, streamline operations, and accelerate time to market for new medications and devices, leading to shorter development cycles and better medical outcomes for patients.

Spotfire Clinical's centralized interface can be integrated with leading clinical development and electronic data capture (EDC) systems, allowing users to leverage interactive visualizations and predictive analytics to rapidly explore their clinical data. Through the platform, clinicians can detect, assess, and understand adverse events, leading to better prevention by integrating with various signal detection systems to mitigate risk associated with ongoing clinical studies.

Users are able to conduct advanced what-if scenarios and sophisticated analysis to gain key insights into data, without the intervention of IT resources or biostatisticians.

"Providing advanced, predictive analytics is one of the powerful benefits of Spotfire in the clinical environment," says Ben McGraw, director of life science industry solutions for Spotfire.

agement tools without the overhead, long-term commitment, and wait that a traditional on-premise im

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Getting It Right in the Emerging Markets

Identifying the opportunities and avoiding the pitfalls in conducting market research in new geographies

FEATURING

Case Studies from China, India and the Middle East that illustrate business issues unique to these markets

DATE and TIME

September 29, 2010

10:30 am — 12:00 pm EDT

With the challenges facing our industry in the more developed markets of the U.S., Western Europe and Japan, the Emerging Markets have become the growth engine for many businesses. Big Pharma is shifting its investment to new geographies. Nevertheless, in countries where market research is not yet established, online penetration is limited and secondary data sources are nonexistent, the challenge remains how to get the business insights required to guide business strategy in these markets.

Key Takeaways

- Challenges of conducting research in emerging markets, including how to prioritize markets to be included in global projects and whether certain countries can be used as surrogates for others
- Key business issues facing the pharmaceutical industry in different countries and how these can be addressed through market research
- Methodologies that work best in emerging markets and others to avoid
- Guidance on cultural differences between the emerging markets to take into account when analyzing research results
- Case studies from China, India and the Middle East that illustrate business issues unique to these markets and research that Kantar Health has conducted to guide decision-making

Who Should Attend

- C-Level Executives
- Regional Executives, Country Leaders and Managers
- Global Account Leaders/Managers
- Marketing Executives with an interest in the Emerging Markets
- Market Research Managers

SPEAKERS

Stephen Potts
Managing Director,
Asia-Pacific,
Middle East and Africa
Kantar Health

Hettie Han
Director,
China
Kantar Health

Gauri Pathak
General Manager,
India
Kantar Health

Sherif Shafick
General Manager,
Middle East and Africa
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Chiltern Solution **CONSOLIDATES STUDY DATA**

Chiltern International has launched Collaborative Technologies, a turnkey solution that offers a single access point to clinical study data as well as a central document repository for the entire study team.

The tool provides clients with one consolidated view of the collected information.

The Collaborative Technologies platform has been configured to work with Chiltern's proprietary systems, as well as widely used EDC and adverse event management tools from providers such as Medidata and Phase Forward.

"A key benefit of Collaborative Technologies is the immediate, global access to current study information, which means faster decisions can be made on the study, resulting in time and cost savings for our clients," says Chiltern CEO Glenn Kerkhof.

The solution has been configured to work with our clinical trial management system and our trial master file and electronic records management system, says Dr. Jim Esinhart.

"Collaborative Technologies offers pharmaceutical companies a suite of best-in-class technological solutions for their clinical trial needs under one organization," adds Jim Esinhart, Ph.D., executive VP, global biometrics and North America of Chiltern.

For more information, visit chiltern.com

Perceptive's Web-Based Tool Provides Easy **STUDY-DESIGN ACCESS**

Perceptive Informatics has introduced a web-based DataLabs Designer module as part of its DataLabs electronic data capture (EDC) solution.

The new tool provides worlwdie clinical study teams with online access to design trials collaboratively.

The study design tool empowers sponsors to have enhanced oversight of the study design process and to track progress.

Its web-based access facilitates the use of a centralized, controlled library of study design components that can be validated, tested, and available for reuse on all new studies.

"Optimizing the trial process is a key priority for the biopharmaceutical industry, and the release of this Web-based version of our study design tool reinforces Perceptive's commitment to provide advanced functionality in our EDC solution to simplify user workflow," says David Stein, senior director, product management, Perceptive Informatics.

The DataLabs Designer tool was developed with the flexibility to be implemented in the customer's environment or hosted by Perceptive, says David Stein.

For more information, visit perceptive.com.

PharmaPros Service Aimed at Smaller Companies' **DATA MANAGEMENT NEEDS**

PharmaPros' eClinical OnDemand service is a targeted new resource that enables small-to-midsized pharmaceutical companies to leverage an integrated e-clinical suite of tools through a cost-effective subscription model.

Working with the small-to-midsized market for many years, we understand the challenges they face in managing today's complex clinical technology landscape, says Peg Regan.

eClinical OnDemand is a technology-neutral, software-as-a-service (SaaS) solution that offers clients the option to incorporate other data sources, such as central laboratories and imaging centers.

The solution also includes a preconfigured e-clinical suite integrated by PharmaPros' Dataflow Manager and incorporating several Phase Forward data management solutions, including InForm GTM, Clintrial CDMS, and Empirica Trace.

"With the small-to-midsized market segment developing some of the most exciting products in biopharmaceutical and device research, we believe we can have a positive impact on these companies by providing them with best-in-class technology through a cost-effective and simplified service model," says Peg Regan, president and CEO of PharmaPros.

Additionally, eClinical OnDemand offers support for loading and reconciliation of external data sources.

For more information, visit pharmapros.com.

ICON Application Enables Swift **PHYSICIAN RESPONSE TO SAFETY SIGNALS**

We can drive down development costs for sponsors while offering 24/7, global access to the latest laboratory data, including detailed analysis of potential trends, signals, alerts, and patient-specific data, says Tom O'Leary.

The IcoLabs Medical Review Application (IMRA), developed and marketed by ICON, is a web-based laboratory application that enables the more efficient use of medical monitoring time and helps expedite the medical management of clinical study subjects.

IMRA trends and graphs real-time laboratory values, enabling physicians and medical monitors to respond faster to important safety signals earlier in the development process.

On average, with the new application data from the pharmaceutical client is no more than a few hours old, allowing for real-time evaluation of trends, signals, and alerts. Additional features of the new tool include up-to-date alert overviews, intuitive data trending, detailed subject profiling, and comprehensive data export tools.

"IMRA satisfies an important need in clinical trials by reducing data review times, which in turn improves the management of study subjects and enables physicians to expedite the medical management of clinically significant findings," says Tom O'Leary, president of Icon Central Laboratories.

For more information, visit iconplc.com

Datatrak Solution Focuses on **PATIENT SAFETY**

The Safety Case Manager creates data reconciliation efficiencies and complements existing safety functions, says Laurence Birch.

Datatrak International has added a Datatrak Safety Case Manager module to its unified clinical research platform aimed at providing additional risk mitigation for patients participating in clinical trials.The Datatrak Safety Case Manager collects individual case safety report data and exports the data in E2B XML format.

"We are pleased to leverage the capabilities of our unique, unified platform to minimize the risk to patients who participate in clinical studies," says Datatrak Chairman Laurence Birch.

For more information, visit datatrak.net.

INC Research Solution Aims for **ACTIONABLE DATA**

When the focus of a clinical trial shifts from patients to data during QualityFinish, we want the entire team to collaborate on project deliverables to keep the trial on time and on budget, says John Potthoff.

INC Research has added a QualityFinish Camp component to the last phase of its clinical study process, with the goal of reducing cycle time and rework for closeout activities and documents. QualityFinish Camp adopts proven project management techniques used in INC's early-phase QuickStart Camp in an effort to reinforce the commitment and project ownership built into the preceding phases.

"When the focus of a clinical trial shifts from patients to data during QualityFinish, we want the entire clinical team to collaborate on project deliverables to keep the trial on time and on budget," says John Potthoff, chief operating officer for INC Research.

For more information, visit incresearch.com.

BBK Implements **FRANCHISE MODEL FOR RECRUITMENT**

Franchise programs create exponential savings through the economies of scale derived from applying strategies and tactics across multiple studies and countries, says Joan Bachenheimer.

BBK Worldwide's Patient Recruitment Franchise Program is a model that creates savings through economies of scale derived from applying strategies and tactics across multiple studies and countries. The franchise model also supports quick, efficient enrollment for multiple studies within the same therapeutic category.

"Using the model of the Patient Recruitment Franchise Program, sponsors are able to consolidate planning and recruitment strategies for immediate and long-term cost reductions that far exceed preferred pricing or volume discounts," says Joan Bachenheimer, BBK Worldwide founding principal and CEO.

For more information, visit bbkworlwide.com.

Accelrys Unveils **ANALYTICS R&D SOFTWARE**

With the expertise required to develop advanced predictive models in short supply, organizations need better ways to capture this specialized knowledge, says Dr. Frank Brown.

Accelrys has released the Materials Studio Collection for Pipeline Pilot, a software solution that enables R&D organizations to integrate predictive analytics for materials properties seamlessly into their scientific workflows.

The solution extends Accelrys' Pipeline Pilot scientific informatics platform to include key materials modeling and simulation tools from the company's Materials Studio application, offering a combination that increases research productivity across the scientific enterprise.

The solution's predictive analytics component allows for a streamlined approach to materials discovery, which can improve a researcher's productivity.

"The Materials Studio Collection helps R&D organizations close this critical gap by more effectively leveraging the skills of expert modelers and making their research results more widely available to other scientists," notes Frank Brown, Ph.D., senior VP and chief science officer of Accelrys.

For more information, visit accelrys.com.

E-Course Series Targets **PHARMA SALES TRAINING NEEDS**

Many companies are deploying new commercial models, which involve fundamental changes in the traditional roles of the sales representative, says Garry O'Grady.

Pharmaceutical Institute has added a new e-course, the Beacon Series on Pharmaceutical and Biotech Sales, designed to address the changing training needs of sales representatives and front-line managers.

The Beacon Series consists of in-depth e-courses focused on nontraditional topics at the heart of the industry's new sales models, including business acumen, managed markets, and selling strategies for the primary care, specialty, and hospital settings.

"The pharmaceutical industry is in a state of transition, causing many companies to make significant changes to the way they do business," notes General Manager Garry O'Grady. "To remain competitive in this increasingly complex environment, many companies are deploying new commercial models, which involve fundamental changes in the traditional roles of the sales representative and the front-line manager."

For more information, visit pharmainstitute.com.

BioClinica Solution Includes CONSORTIUM-DEVELOPED METRICS

BioClinica now offers a reporting solution that incorporates the industry-standard performance metrics for clinical trials as defined by the Metrics Champion Consortium (MCC), an open, collaborative organization dedicated to fostering the development of common performance metrics for both sponsors and service providers in support of an improved drug development process. BioClinica is a corporate sponsor of the MCC and has supported the definition of both imaging and clinical trials metrics through its participation in the consortium.

"BioClinica is a vigorous supporter of standards initiatives such as the MCC and CDISC," says Peter Benton, president of BioClinica's eClinical division. "Standards help the industry drive efficiency and facilitate transparency of the data associated with clinical trials."

Unlike other solutions, this platform untethers the clinical data, making the data more easily accessible and therefore more usable, says Mark Weinstein.

"As we approach the release of MCC Clinical Trial Performance Metrics version 1.0, we are pleased by the enthusiasm of MCC members preparing to be able to track and report the metrics," says MCC President Guy Mascaro. "The BioClinica reporting system is a good example of how MCC members are helping us move forward with fulfilling our mission of providing the platforms, tools, and shared learning opportunities that encourage performance improvement, effectiveness, efficiency, and appropriate levels of control in the drug development process."

In other news, BioClinica's recently introduced BioClinica Integrated Operations Platform (BIOP) leverages the popular Microsoft Office and SharePoint platforms to deliver a real-world window on clinical operations across studies and clinical technologies.

"Through our work with Microsoft we are embracing the SharePoint and Office tools that many customers already have and use," says Mark Weinstein, CEO of BioClinica.

"With the integration of our Office and SharePoint platforms, BioClinica customers can liberate their data for a comprehensive, real-time view into studies and pertinent information, with Office Smart clinical-trial management systems," adds Michael Naimoli, director of life sciences industry solutions, Microsoft.

For more information, visit bioclinica.com.

InnovoCommerce Incorporates New Microsoft SHAREPOINT RELEASE

InnovoCommerce has released a compliance offering utilizing Microsoft SharePoint 2010 that aims to help life-sciences organizations rapidly and cost-effectively meet FDA 21 CFR Part 11 and other regulatory compliance requirements.

The new offering allows InnovoCommerce clients to configure, extend, and deploy SharePoint 2010 in a validated state with no need for expensive bolt-on compliance software. Once an enterprise purchases its SharePoint 2010 licenses, the InnovoCommerce team executes the turnkey compliance offering, which includes reusable consulting components and SharePoint Qualification tools.

For more information, visit innovocommerce.com.

PHT, Entra Health Provide Integrated CLINICAL TRIALS TECHNOLOGY FOR DIABETES

PHT and Entra Health Systems are partnering to provide integrated data monitoring technology for the management of clinical trials for the treatment of diabetes and in trials where blood glucose management plays a critical role in the investigation.

With the MyGlucoHealth Wireless meter we can monitor in real time not just blood glucose readings, but when and how often patients are testing, says Richard Strobridge of Entra Health.

The solution combines Entra Health's MyGlucoHealth Wireless blood glucose meter with PHT's electronic patient reported outcome (ePRO) system to create an automated glucose monitoring and ePRO solution.

The integration between PHT's hand-held technology and the MyGlucoHealth's wireless, Bluetooth-enabled glucometer provides maximum ease of use for patients while improving data flow and ensuring participation and compliance. The system improves safety and rewards researchers with more accurate real-time data from every clinical-trial patient on a daily basis.

"Clinical investigators now have direct access to real-time blood glucose data during clinical trials, and patient-related inaccuracies are eliminated," explains Richard Strobridge, CEO of Entra Health Systems.

"Research studies have shown handwritten paper log book entries of glucose data contain numerous errors both in transcription and time accuracy," adds Philip Lee, president and CEO of PHT. "Waiting to download or transcribe this critical data leads to delays and poor clinical-trial data quality."

For more information, visit entrahealthsystems.com.

For more information, visit phtcorp.com.

Pipeline Search Tool Integrates REAL-TIME INTELLIGENCE with Comprehensive Data

Elsevier and InfoDesk are co-developing a federated drug pipeline intelligence solution for pharmaceutical and life-sciences companies, with the goal of increasing productivity and improving quality of results securely inside or outside of a customer's firewall.

Building on the sophisticated synonym index developed as part of the Universal Integrator project initiated by Elsevier in 2007, InfoDesk is applying its knowledge and experience to develop the new search tool.

Also, unlike other externally hosted Web-based products, Elsevier and InfoDesk's new product can be hosted or installed inside a customer's firewall for greater security.

The first search tool release is expected to be available in the second half of 2010, with additional modules expected in 2011 that will give customers the opportunity to expand their federated search and integrate their proprietary internal data.

"We've noticed our pharmaceutical customers are frustrated with the way drug pipeline data are presented," observes Sterling Stites, president and CEO of InfoDesk. "There are many robust databases in the marketplace, but with the possible exception of a few information specialists, nobody actually likes the process of using databases. Consequently, database usage statistics are often disappointing."

For more information, visit elsevier.com.

For more information, visit infodesk.com.

Nextrials, Formedix Collaborate on CLINICAL TRIAL DATABASE DESIGN TOOL

The integration of Nextrials' Prism electronic data capture and clinical trial data management platform with Formedix's Origin study design tools enables Prism users to easily build customized databases with just a few mouse clicks, reducing the length and cost of clinical trials by expediting study start-up through reduced specification and development effort.

"We are always looking for ways to add features and functionality to Prism," says James Rogers, CEO and co-founder of Nextrials. "By partnering with Formedix, we've given users a powerful but easy-to-use tool to design clinical trial databases that includes the ability to automatically generate annotated electronic case report forms (CRFs), database design specifications, and create submission-ready CRFs."

By partnering with Nextrials, we foster another pipeline to small- to mid-range research organizations that could benefit from our product features, says Mark Wheeldon of Formedix.

"Through our partnership with Nextrials, we foster another pipeline to small- to mid-range research organizations that could benefit from our product features, particularly the reuse of libraries of forms, items, and codelists for creating databases," says Mark Wheeldon, founder and CEO of Formedix.

For more information about Formedix, visit formedix.com.

For more information about Nextrials, visit nextrials.com.

Y Brand Launches NEW WEBSITE

Y Brand recently launched a new website, ybrand.com, designed to engage visitors by asking the 'why' questions that lead to great branding insights.

The landing page of the site features a rotating series of questions — for example, "Why do onions make you cry?" or "Why is the earth round?" — then interprets these questions to make a connection to branding-oriented questions such as "Why is my brand's category shaped the way it is?" The answers to the original questions are revealed at the bottom of the page when visitors scroll over the question.

Pharma companies often fail to consider the most important question: why? says Vince Parry.

"When thinking about brands, many companies ask the 'who, what, where, how' questions: What does the therapy do? Who is the target audience? How does it work? But often they fail to consider the most important question: why?" observes President Vince Parry. "Y Brand was founded on the principles of answering 'why' questions to get at the core beliefs that create indelible bonds between brands and customers: why they buy, rather than how we sell."

The new site also works to engage customers in direct dialogue about the branding challenges they may be facing. Within the About You section, visitors can select from a series of branding questions developed with healthcare clients in mind — such as "Do you need to drive brand distinction through class branding?" — then review advice and case studies that address the need.

For more information, visit ybrand.com.

ValueTrak Module Integrates DATA

ValueCentric has added a prescription reporting module to its ValueTrak data and services platform that delivers the ability to drill down to specific pharmacy locations to view product performance, market trends, and patient demographics.

The accurate, actionable data provided by Prescription Reporting in ValueTrak can be used throughout the enterprise, bridging the gap between trade and commercial teams and unifying the data in one, on-demand, easy-to-use platform.

"The integration of trade channel and prescription data is just the beginning of a data revolution," observes Dave Janca, founder and CEO of ValueCentric. "Technology will continue to play an increasingly important role in the access of data, its timeliness, the integration of data and content, and ease of delivery."

For more information, visit valuecentric.com.

PharmaMarker Supports Compliance with SUPPLY-CHAIN REGULATIONS

Not only is this system capable of handling new track and trace regulations coming into place now but also those expected in the future, says Frank Madden of Crest Solutions.

PharmaMarker, a new track and trace packaging system from Eisai Machinery U.S.A. and Ireland's Crest Solutions, is designed to help pharmaceutical manufacturers meet the challenges of more stringent local and international regulations in the areas of coding and traceability of pharmaceutical products.

With many countries and states introducing their own regulations to help ensure a more secure supply-chain management system in the area of pharmaceutical production and delivery to end users, it is more challenging than ever for the pharmaceutical industry to ensure it is addressing new coding and traceability regulations as they are implemented.

The PharmaMarker system has been developed to meet these challenges by coding, verifying, and tracking up to 450 pharmaceutical cartons per minute, ensuring they can be fully traced along any point in their production life cycle.

The system marks the product cartons with a data matrix code, which it then verifies to determine the 'pass' or 'fail' path that the carton then follows along the production line.

Cartons that pass the verification station have their code details commissioned on Crest Solutions' Protrack traceability software database, which can be shared with regulatory or enterprise resource planning (ERP) environments, such as SAP.

"The PharmaMarker is an easy-to-integrate, easy-to-validate solution for tracking and tracing pharmaceutical products, thus enabling manufacturers to immediately comply with ongoing regulations while also improving patient safety, counteracting fraud, and creating a more secure supply chain," says Michael de la Montaigne, president of Eisai Machinery U.S.A.

"There is significant market potential for this product as companies need to comply with new regulations," adds Crest Solutions CEO Frank Madden.

For more information, visit crestsolutions.ie.

For more information, visit eisaiusa.com.

Qumas Compliance Solution Harnesses Microsoft **SHAREPOINT 2010**

Qumas has introduced an enterprise compliance solution for Microsoft SharePoint 2010 that offers customers the ability to manage compliance documents, records, and other content on a single platform.

"We have been approached by a number of firms that intend to make SharePoint 2010 a cornerstone of their technology infrastructure," explains Qumas CEO Kevin O'Leary. "Our life-sciences expertise and relationship with Microsoft allows us to offer them a

We recognize the game changing impact that SharePoint is having on the technology landscape, says Kevin O'Leary.

rich, scalable compliance solution that takes full advantage of their investment."

The Qumas Compliance Solution provides an intuitive environment for end-users by adding solution-specific functionality that leverages and extends the underlying SharePoint platform to support industry demands in a number of key areas, including manufacturing controlled documents, policies and procedures, customer complaints, and R&D document control. The solution also helps clients reduce risk through features such as enforced retention schedules and tagged content.

For more information, visit qumas.com.

Thomson Reuters Registry Improves **DRUG DEVELOPMENT PARTNERING**

Thomson Reuters has launched The Outpartnering Registry, a free resource designed to help biotechnology, pharmaceutical, and academic organizations with drugs in development find partnering opportunities around the world.

The registry enables authorized users to share essential information about their company and drug pipeline with potential partners.

Organizations can indicate which of their programs and drugs are available for partnering and, optionally, what type of partnership they are seeking in which regions of the world. They can also add and update partnering contacts together with links to LinkedIn profiles and increase networking opportunities by displaying attendance at partnering conferences.

"Pharma companies need new and innovative ways to share the financial risk of developing drugs," says Mark Gordon, director of product strategy at Thomson Reuters.

"This new initiative benefits both drug innovators, who can easily update their partnering information online, as well as in-licensors, who can quickly find assets available for partnering."

In other news, Thomson Reuters has released Advantage Suite 5.0, the newest version of the company's decision support system for healthcare payers. The update includes new features such as dashboard customizing capabilities, a redesigned interface, and Web access that accommodates the workflow needs of data analysts and business managers.

For more information, visit thomsonreuters.com.

E-UPGRADES AND ENHANCEMENTS

- Version 3.0 of **EPHARMASOLUTIONS'** electronic monitor visit report (eMVR) has new features to support online and offline completion of monitoring reports for traveling clinical research associates and integrations with leading clinical trial management systems (CTMS).

  For more information, visit epharmasolutions.com.
- The latest version of the Regulatory Solutions Suite (RSS) from **IMAGE SOLUTIONS (ISI)** offers new features and functionality to accommodate the specialized requirements of the Japanese pharmaceutical market, as well as an enhanced Japanese user interface to give companies greater flexibility to manage electronic common technical document (eCTD) and paper submissions. ISI's improved RSS product also includes specific functionality addressing the stepwise adoption of eCTD in Switzerland, with a defined roadmap to address new and ongoing requirements.

  For more information, visit imagesolutions.com.
- **INTRALINKS** has unveiled an enhanced version of its SaaS-based Safety Document Exchange, a scalable solution for safety teams that manage reporting for SAEs around the world. Key enhancements include configurable rules-based automated workflow, intuitive organization and user-based views, and detailed compliance reporting.

  For more information, visit intralinks.com.
- **NEXTRIALS** has launched a Prism clinical trial data management platform application for Apple's iPad and iPhone devices. The application supports mobile access to patient data in clinical trial and healthcare settings and is available as a free download through the Apple iTunes Store.

  For more information, visit nextrials.com.
- The latest version of **SPARTA SYSTEMS'** enterprise quality management software solution, TrackWise 8, provides new capabilities that enable the rapid, parallel deployment of business processes in enterprise environments, as well as increases usability for the infrequent user.

  For more information, visit sparta-systems.com.
- **TCN E-SYSTEMS** has created a smartphone application for its patient recruitment technology, enabling users to make more rapid business decisions regarding trial management through broader access to real-time recruitment metrics.

  In addition, Version 5.2 of TrialCentralNet features additional languages in its library, including Chinese, Dutch, English, French, German, Hindi, Italian, Japanese, Polish, Portuguese, Russian, and Spanish.

  For more information, visit bbkworldwide.com.